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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,425	11/15/2000	Leonard Presta	P1726R1P1	3384

7590 10/02/2002

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EXAMINER
SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
713,425	PRESTA
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-79 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-79 ~~is/are rejected~~.

☐ Claim(s) _____ is/are objected to.

☑ Claim(s) 1-79 are subject to restriction or election requirement.

4/2/00

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, 23-30, 38-40, 42, 44, 46-52, 57-59 and 66-67, drawn to engineered antibodies with increased ADCC activity or binding affinity for at least one Fc gamma receptor (irrespective of whether or not binding affinity is reduced for another such receptor), classified in class 424, subclass 133.1 and class 530, subclass 387.3.

II. Claims 14-22, 36-37, 41, 43 and 57-59, drawn to engineered antibodies with decreased binding affinity for at least one Fc gamma receptor, classified in class 424, subclass 133.1 and class 530, subclass 387.3.

III. Claims 31-33, 45, 53 and 64-65, drawn to polypeptides with reduced binding affinity for an FcRn, classified in class 530, subclass 387.1.

IV. Claims 31, 34-35, 45, 54-56 and 64-65, drawn to polypeptides with increased binding affinity for an FcRn, classified in class 530, subclass 387.1.

V. Claims 68-72, drawn to nucleic acids, vectors, host cells, and methods of producing a polypeptide with increased ADCC activity or binding affinity for an Fc gamma receptor, classified in class 435, subclass 69.6.

VI. Claim 73, drawn to a method of treating a disorder with polypeptides with increased ADCC activity or binding affinity for an Fc gamma receptor, classified in class 424, subclass 133.1.

VII. Claims 74-79, drawn to methods of selecting a variant Fc having altered FcR binding or altered ADCC wherein the alteration is an increase in these activities, classified in class 435, subclass 7.1+.

VIII. Claims 74-75 and 77-79, drawn to methods of selecting a variant Fc having altered FcR binding or altered ADCC wherein the alteration is a decrease in these activities, classified in class 435, subclass 7.1+.

IX. Claims 60-63, drawn to polypeptides with an increased binding affinity for an Fc gamma Receptor allotype, classified in class 424, subclass 131 and class 530, subclass 387.3.

X. Claims 60-63, drawn to polypeptides with a decreased binding affinity for an Fc gamma Receptor allotype, classified in class 424, subclass 131 and class 530, subclass 387.3.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV and IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products having increased and the products having decreased binding affinities have different properties and functions and different motivations for their production (note, the examiner considers any claim drawn to a polypeptide having increased binding affinity for one species of Fc gamma receptor and a decreased binding affinity for a second species of Fc gamma receptor as falling within Group I and not Group II). Furthermore, Fc gamma receptors and FcRn receptors have distinct functions; the motivation to make changes in binding affinities for various Fc gamma receptors appears to be related to a desire to alter ADCC activity, while the motivation to make changes in the binding affinities for FcRn receptors appears to be related to a desire to make changes in clearance rates. Also, motivation to provide polypeptides with altered

binding affinities for Fc gamma Receptor allotypes (Groups IX and X) would differ from the motivation to provide the altered polypeptides of the other Groups. Therefore, the searches for the inventions of Groups I-IV and IX-X would require searches for distinct products.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct because the polypeptide of Group I and the nucleic acid/vector/host cell of Group V have different physiochemical properties and have different uses.

It is further noted that the method of Group V would not be used to produce the polypeptides of Groups II-IV or IX-X.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group I could be used in the isolation of cells bearing a particular Fc receptor, or could be used in an in vitro immunoassay in which Fc receptors are used to capture antibody reagents onto a solid phase.

It is further noted that the products of Groups II-IV and X would not be used in the method of Group VI

Inventions VII (or VIII) and I (or II) are related as process of making (screening for) and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that

the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide products of Group I (or II) could have been obtained by other methods (e.g. by screening for alterations in other effector function activities of the altered polypeptides).

The methods of Groups VII and VIII differ in that the nature and properties of the polypeptide product for which one is screening and are thus distinct.

Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

In the event that any of Groups I, II or V-X are elected, the following election of species is required:

Claims 1-5, 8-16, 23, 46-52, 57-61, 64-76 and 78-79 are generic to a plurality of disclosed patentably distinct species comprising antibodies (or nucleic acids encoding antibodies, methods of use of the antibodies, or methods of selection of the antibodies) wherein the antibodies can have increased or decreased binding affinities for distinct receptors, such as Fc gamma RI, Fc gamma RII, and Fc gamma RIII. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of antibody (or nucleic acid encoding, or method of use, or method of selecting such) having increased or decreased binding affinity for a particular species Fc gamma receptor, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders whose telephone number is 703-308-3976. The examiner can normally be reached on Mon.-Thu., 8:15 am-5:45 pm and on alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone number for a response to restrictions is 703-308-3704; use attached form.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAS
October 1, 2002

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644